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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,542	12/27/2001	Kyung-Ja Han	2669-0117P	9476

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,542	HAN, KYUNG-JA	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-28-2004 has been entered.

The amendment filed on 1-29-2004 has been entered. Claim 1 has been amended. Claims 1 and 2 are pending and currently under examination.

Claim Rejections Withdrawn

The new matter rejection of claims 1-2 under 35 U.S.C. 112, first paragraph, based on the recitation of the phrase "staining red blood cells isolated as the sample" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained and New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained for reasons of record. See MPEP § 2172.01. The stated goal of the amended claim is to diagnose hemolytic anemia. The amendment to said claim is insufficient to overcome the rejection. There is no correlation between the recited steps of staining red blood cells with anti-hemoglobin antibody to identify the quantity of fragmented red blood cells and indented red blood cells and the stated goal of the claimed method. How does the ratio of fragmented and indented red blood cells correlate to a diagnosis of hemolytic anemia?

Claim 1 is rendered vague and indefinite by the use of the phrase "wherein said diagnostic method of hemolytic anemia shows stained red blood cells of more than 1%". It is unclear what is meant by said phrase. Is "1%" considered the background level of the recited method or the threshold for the diagnosis of hemolytic anemia? As written it is impossible to determine the metes and bounds of the claimed invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite, "peripheral blood sample in **hypotonic solution** with PE conjugated anti-hemoglobin (anti-Hb) antibody". This phrase does not

appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification is recites the use of NaCl in concentrations from 0.2% to 2% wherein only the concentration of 0.6% is deemed to be useful (see page 4, lines 20-22). Therefore this limitation is new matter.

Applicant has amended claim 1 to recite, "wherein said diagnostic method of **hemolytic anemia** shows stained red blood cells of more than 1%". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification recites a correlation of RBC staining with MAHA, malaria, spherocytosis and postsplenectomy patients (see Table 1 and pages 6-9). Therefore this limitation is new matter.

Applicant has amended claim 2 to recite, "2ml". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification recites the use of samples with the volume of 2μ not 2 ml. Therefore this limitation is new matter.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant invention is drawn to methods of diagnosis hemolytic anemia which comprise detecting the number of damaged red blood cells by treating a peripheral blood sample with a PE conjugated anti-hemoglobin antibody; diluting said sample in saline and analyzing said sample by flow cytometry. The diagnosis of hemolytic anemia is made when more than 1% of the red blood cells in the sample are stained. Based on the instant disclosure the claimed method would not allow one of skill in the art to determine if a given patient suffers from hemolytic anemia. The specification discloses that the use of the claimed method resulted in the staining of 2.95% ± a standard deviation of 2.95 of the red blood cells from samples obtained from patients with microangiopathic hemolytic anemia (MAHA) compared to 0.55 ± 0.23 % in samples from normal patients (control). There is no statistical difference between the results obtained from the MAHA samples and the normal samples. Moreover, there is no statistical significance between the results obtained from the MAHA samples and samples from malaria patients, postsplenectomy patients and patients suffering from spherocytosis. Consequently, based in the specification one would not be able to determine whether a given patient was suffering from hemolytic anemia by using the claimed method. Therefore, the instant invention is not enabled.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
June 22, 2004

LYNETTE R. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600